MAR 1 2002

510(k) Summary
Vigil™ Lipid Control

K020521

1.0 Submitted By

Gail Lefebvre
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2.0 Date Submitted

February 14, 2002

3.0 Device Name(s)

3.1 Proprietary Names

Vigil™ Lipid Control

3.2 Classification Names

Quality Control Material (assayed and unassayed) (21 CFR § 862.1660)

4.0 Legally Marketed Device

The Beckman Coulter Vigil Lipid Control claims substantial equivalence to the Beckman Coulter Vigil Lipid Control currently in commercial distribution, FDA 510(k) Number K974452.

5.0 Device Description

The Vigil Lipid Controls are four-level, ready-to-use human serum-based liquid controls manufactured by Beckman Coulter, Inc. Each kit contains 4 X 4 mL bottles of a single level of control. Vigil Lipid Controls are made from stabilized human serum and are designed to monitor the reliability of manual and automated *in vitro* diagnostic assays of lipid analytes in the clinical laboratory. Vigil Lipid Control serum is derived from human plasma that has been defibrinated and then stabilized by freezing at temperature between -15°C and -20°C.

6.0 Intended Use

Vigil Lipid Control stabilized liquid-control serums are intended for monitoring the reliability of manual and automated *in vitro* diagnostic assays of lipid analytes. The values for this control have been established using Beckman Coulter Reagents on Beckman Coulter Clinical Analyzers, and are specific for those systems. The use of three or more levels of control enables the laboratorian to monitor changes in calibration linearity along with analytical error and imprecision.

7.0 Comparison to the Predicate (Description of the Modification to the Legally Marketed Device)

The Intended Use statement for the Vigil Lipid Control has been reworded to a generic statement for lipid analytes. Value assignment for Beckman Coulter's SYNCHRON Systems LDL Cholesterol (LDLD) and Direct HDL (HDLD) assays have been added to the product insert.

8.0 Summary of Performance Data

Performance data from validation testing supports equivalency.

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR § 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 2002

Ms. Gail Lefebvre
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Box 8000
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Re: k020521
Trade/Device Name: Vigil™ Lipid Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Code: JJY
Dated: February 14, 2002
Received: February 19, 2002

Dear Ms. Lefebvre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): To be assigned K020521

Device Name: **Vigil™ Lipid Control**

Indications for Use:

Vigil Lipid Control stabilized liquid-control serums are intended for monitoring the reliability of manual and automated *in vitro* diagnostic assays of lipid analytes. The values for this control have been established using Beckman Coulter Reagents on Beckman Coulter Clinical Analyzers, and are specific for those systems. The use of three or more levels of control enables the laboratorian to monitor changes in calibration linearity along with analytical error and imprecision.

(Division Sign-Off)
Division of Clinical L
510(k) Number K020521

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR § 801.109) Optional Format 1-2-96